Cogstate Responses to YPrime Rater Training Questions
04 Aug 2023
Ken Billard, Chief Commercial Officer

1. **Please provide a list of rater trainings/certifications available, including a description for the training/certification process for each.**

Cogstate designs and delivers customized risk-based rater training programs that combine an understanding of trial objectives with our knowledge of assessments and common rater error patterns. Included is a list of **50 scales we train on most frequently**. We invite you to ask us about the availability of specific scales if you do not see them included, **as we have trained on 150+ scales.**

At Cogstate, we use proven methodologies and leading technology to support all aspects of scale management, rater training and central monitoring in global clinical trials.

The Cogstate Rater Training Program is a rater selection, instruction, engagement, and management program that provides flexible and effective rater training. Cogstate's Rater Training Program eliminates unnecessary training, minimizes rater burden during study start-up, shortens overall training time for sites and reduces overall costs related to training.

The preferred Cogstate Rater Training and Certification program is entirely remote. Remote training allows learning to take place at a rate consistent with the raters' ability to understand concepts conveyed and to practice in a comfortable, or familiar setting. The limited time available at investigator meetings (IMs) and the amount of new information at IMs can be overwhelming to some raters. Learning theory and research are clear that learning that is distributed over time and in the setting where the recall of the information will need to take place is superior to concentrated learning and learning in a dissimilar setting.

While training and certification is customized to the study itself, it usually requires completion of an eLearning activity. The eLearning activity allows for both scale-experienced raters and developing raters to receive a customized training experience based on the rater's own progress through the learning activity. More experienced raters can waive most of the content and proceed directly to the culminating activity designed to demonstrate mastery in the administration and scoring of the scale.

We also support other training modalities, like practice administrations with data source reviews and applied training, as is appropriate for specific studies and raters' training needs.

ABAS-3 (Adaptive Behavior Assessment System, 3rd Edition)
ABC (Aberrant Behavior Checklist)
ADAMS (Anxiety, Depression and Mood Scale)
ADAS-Cog (Alzheimer's Disease Assessment Scale)
ADCS-ADL (Alzheimer's Disease Cooperative Study - Activities of Daily Living)
BASC-3 (Behavior Assessment for Children, Third Edition)

Bayley-III (Bayley Scales of Infant and Toddler Development, 3rd Edition)
BRIEF (Behavior Rating Inventory of Executive Function)
C-SSRS (Columbia Suicide Severity Rating Scale)
CareCGI (Caregiver Global Impression)
CBCL (Child Behavior Checklist)
CDR (Clinical Dementia Rating)
CFT (Category Fluency Test)
CGI (Clinical Global Impression) / CGI-C / CGI-S
COWAT (Controlled Oral Word Association Test)
CSHQ (Child's Sleep Habits Questionnaire)
D-KEFS Verbal Fluency
EQ-5-5L Overview (EuroQol)
ESS (Epworth Sleepiness Scale)
FAQ (Functional Abilities Questionnaire)
GDS (Geriatric Depression Scale)
HVLT (Hopkins Verbal Learning Test)
LFT (Letter Fluency Test)
MHIS (Modified Hachinski Ischemic Scale)
MoCA (Montreal Cognitive Assessment)
MMSE (Mini Mental State Examination)
Mullen (Mullen Scales of Early Learning)
NPI (Neuropsychiatric Inventory-Questionnaire)
Preclinical Alzheimer’s Cognitive Composite (PACC)
PedsQL Core (Pediatric Quality of Life Inventory - Core)
PedsQL F.I. (Pediatric Quality of Life Inventory - Family Impact)
PGI (Parent Global Impression Scale)
PSQI (Pittsburgh Sleep Quality Index)
QOL-AD (Quality of Life for Alzheimer's Disease)
RAVLT (Rey Auditory Verbal Learning Test)
RBANS (Repeatable Battery for the Assessment of Neuropsychological Status)
RBS-R (Repetitive Behavior Scale - Revised)
RUD-Lite (Resource Utilization in Dementia - Lite)
Sensory 2 (Short Sensory Profile-2)
TMT (Trail Making Test)
Unified Parkinson Disease Rating Scale (UPDRS)
VABS 2/3 (Vineland Adaptive Behavior, 2nd and 3rd Edition)
VAS (Visual Analog Scale)
WAIS-III - DSC (Wechsler Adult Intelligent Scale 3rd Edition - Digit Symbol-Coding)

WAIS-IV DS (Wechsler Adult Intelligent Scale 4th Edition - Digit Span)
WAIS-IV DSC (Wechsler Adult Intelligent Scale 4th Edition - Digit Symbol Coding)
WASI-II (Wechsler Abbreviated Scale of Intelligence- Second Edition)
WPPSI-IV (Wechsler Preschool and Primary Scale of Intelligence, 4th Edition)

2. **Please provide a list of metrics available to measure inter-rater reliability/validity and describe the Provider process/support to Client for monitoring inter-rater reliability and validity/controlling rater drift, where applicable.**

Cogstate utilizes a variety of training and certification methods prior to the first subject visit to assess inter-rater reliability and test/scale competency. These methods vary by type of scale, role of the scale in the study, phase of research, etc. Metrics may include the number and severity of administration errors, scoring errors, and response-recording errors yielded during an audio-recorded "practice administration" for key scales. Raters' practice administrations are reviewed by one of our Local Expert Advisors (LEADs) according to a detailed and systematic review template. Pass/fail criteria are established to determine whether raters can be certified or require remedial training. Competency or mastery may also be in the form of knowledge quizzes, scoring of training videos, or mock source documents, in comparison to gold-standard scores. Some of these methods lend themselves to summary inter-rater reliability statistics, such as kappa and other statistical measures of concordance.

Cogstate utilizes several methods to monitor in-study rater performance on an individual basis, which are augmented by algorithm-based review of data as captured in the study's EDC/database (e.g., to detect scores that are outliers for the study population, represent unusual change scores from one administration to the next for same subject, or that represent other unlikely patterns of scores within and across scales as determined by Cogstate scientists). Methods vary from study to study, depending on phase of research, as well as number and type of scales. Central monitoring of individual rater performance during the study can obviate the need for doing study-wide rater re-calibration events.

Raters are periodically monitored throughout the study using the same or similar types of systematic audio file and source document reviews. Each rater can be checked for drift and given corrective feedback on an ongoing basis during the study. In addition, or instead, depending on the sponsor and study, more formal recalibration exercises with all raters can be used at one or more times during the study. Cogstate also uses formal methods of calibrating our LEADs prior to study start and recalibrating them during study, when study durations are protracted.

3. **Can the reliability metrics be customized for each outcome scale based on the measure's individual psychometric properties, the study population, and study core objectives? Please describe.**

Yes, Cogstate customizes reliability metrics for each outcome measure based on the importance of the particular scale(s) in the study (primary/secondary/exploratory outcome) as well as the complexity of the scale and study population.